

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
John B. SULLIVAN et al.)
)
Serial No. 08/405,454)
)
Filed: March 15, 1995)
)
For: ANTIVENOM COMPOSITION)
CONTAINING FAB FRAGMENTS)
(amended))

Group Art Unit: 1816

Examiner: Ron Schwadron, Ph.D.

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

SECOND DECLARATION OF FINDLAY E. RUSSELL, M.D., PH.D.
UNDER 37 C.F.R. § 1.132

I, Findlay E. Russell, M.D., Ph.D., do hereby declare and say as follows:

1. I am one of the joint inventors of the subject matter disclosed in U.S. patent application Serial No. 08/405,454.

2. Attached hereto as Exhibit 1 are claims 40-49.

3. On information and belief, claims 40-49 of Exhibit 1 are pending in U.S. patent application Serial No. 08/405,454.

4. I have examined claims 40-49 of Exhibit 1, and I believe that I am a joint inventor of the subject matter of these claims.

5. I am a coauthor of an article identified as Sullivan, Russell *et al.* (1984) Protection Against Crotalus Venom Lethality by Monovalent, Polyclonal F(ab) Fragments: In Search of a Better Snake Trap. *Veterinary and Human Toxicology* 26, 400 ("the Sullivan, Russell *et al.* article").

6. I am a joint inventor of the subject matter disclosed in the Sullivan, Russell *et al.* article.

7. I understand that the Examiner cited the Sullivan, Russell *et al.* article against claims 40-49 of U.S. patent application Serial No. 08/405,454 because Ned Egan and Michael Owens are named as coauthors of the Sullivan, Russell *et al.* article, but they are not named as coinventors of U.S. patent application Serial No. 08/405,454.

I also understand that the Examiner asserted that the subject matter claimed in claims 40-49 was not invented by the inventors named in the application.

8. The experimental work described in the Sullivan, Russell *et al.* article was either conducted by John B. Sullivan or myself, or it was performed under our direction or supervision.

9. Ned Egan and Michael Owens performed the isoelectric focusing and antibody separation required to obtain the F(ab) fragments John B. Sullivan and I used in the work reported in the Sullivan, Russell *et al.* article. Dr. Egan performed experimental work under my direction or supervision. Dr. Owens performed experimental work under John B. Sullivan's direction or supervision.

10. Ned Egan and Michael Owens did not make an inventive contribution to the experimental work described in the Sullivan, Russell *et al.* article, nor did they make an

inventive contribution to the subject matter disclosed or claimed in U.S. patent application Serial No. 08/405,454. They are not joint inventors of this subject matter.

11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine, imprisonment, or fine and imprisonment under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of this application or any patent issuing therefrom.

Date:

April 30, 1998

By:

Findlay E. Russell M.D., Ph.D.
Findlay E. Russell, M.D., Ph.D.

Pending Claims of Serial No. 08/405,454

40. An antivenom composition comprising Fab fragments which bind specifically to a venom of a snake of the *Crotalus* genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier, wherein said venom comprises more than one toxin.

41. The antivenin composition of claim 40, wherein an antibody source for said Fab fragments is IgG(T).

42. The antivenin composition of claim 40, wherein an antibody source for said Fab fragments is polyvalent IgG(T).

43. The antivenin composition of claim 40, wherein said Fab fragments are derived from IgG(T).

44. The antivenin composition of claim 40, wherein said Fab fragments are derived from polyvalent IgG(T).

45. Fab fragments which bind specifically to a venom of a snake of the *Crotalus* genus, and which are essentially free from contaminating Fc as determined by

immunoelectrophoresis using an anti-Fc antibody, wherein said venom comprises more than one toxin.

46. The Fab fragments of claim 45, wherein an antibody source for said Fab fragments is IgG(T).

47. The Fab fragments of claim 45, wherein an antibody source for said Fab fragments is polyvalent IgG(T).

48. The Fab fragments of claim 45, wherein said Fab fragments are derived from IgG(T).

49. The Fab fragments of claim 45, wherein said Fab fragments are derived from polyvalent IgG(T).